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RETROSPECTIVE ANALYSIS OF ADVERSE DRUG REACTIONS INDUCED BY ANTIBIOTICS IN A TERTIARY CARE CENTRE

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ABSTRACT

Objective: Adverse drug reaction contributes to a serious problem increasing the morbidity, mortality and health care costs worldwide. This study retrospectively analyses the adverse drug reactions of antibiotics in inpatients of tertiary care centre. **Methods**: This is a retrospective study which analyzes the ADRs of antibiotics in inpatients of Sri Ramachandra Medical College for a period of 1 year (May 2013 to May 2014). ADR reports was collected from the Pharmacovigilance centre and causality assessment was done using WHO (UMC) Uppsala Monitoring Centre. Data was collected from the ADR forms and case sheets. **Results:** Total number of adverse drug reactions for a period of one year was 136 and adverse drug reaction due to antibiotics in our hospital was 97 with the female predominance of 60.Majority of the adverse drug reaction was from the surgery and medicine department and most of the reactions involved skin. Quinolones was the leading antibiotic to produce reaction, others were cephalosporins and extended spectrum penicillins and all the reactions were mostly mild and moderate. **Conclusion**: The awareness and spontaneous reporting and recording of adverse drug reaction of antibiotics and other drugs involves a team work and it is a way of strengthening the regional Pharmacovigilance centre to provide a perfect healthcare system.

KEYWORDS: Morbidity, mortality, hospital.

INTRODUCTION

Adverse drug reaction (ADR) is defined according to WHO as any response to a drug which is noxious and unintended and occurs at doses normally used in man for prophylaxis, diagnosis or therapy of disease or the modification of physiological function. ADRs usually prolong the length of hospital stay, economic burden and increased death. [1] In India ADRs were responsible for large numbers of hospital admissions. In India, 0.7 % ADRs are responsible for hospital admissions and 3.7 % of the hospitalised patients experience ADRs with 1.8 % ADRs being fatal. [2] ADR monitoring is necessary to make drugs safer and due to the inadequacy of the study of drugs in clinical trials. [4] Many studies revealed that the incidence of adverse drug reaction is more common with antibiotics. Antibiotics are used to restore health but it may also turn into serious adverse drug reaction. Although most antibiotics are safe considering their volume of use, some of them have the potential to cause life-threatening side effects. Majority of hospitalized patients are treated with antimicrobial agents and their use account for more than 50% of drug expenditures in hospitals. Most of the ICU patients receive antibiotics for therapy or prophylaxis. This necessitates the need to study the adverse drug reactions related to antibiotics and also to create awareness among the health care professionals and the patients. [3] This study was conducted to report the prevalence of adverse drug reactions due to antibiotics.

OBJECTIVE

Aim of this study is to retrospectively analyse the adverse drug reactions of antibiotics in inpatients of tertiary care centre.

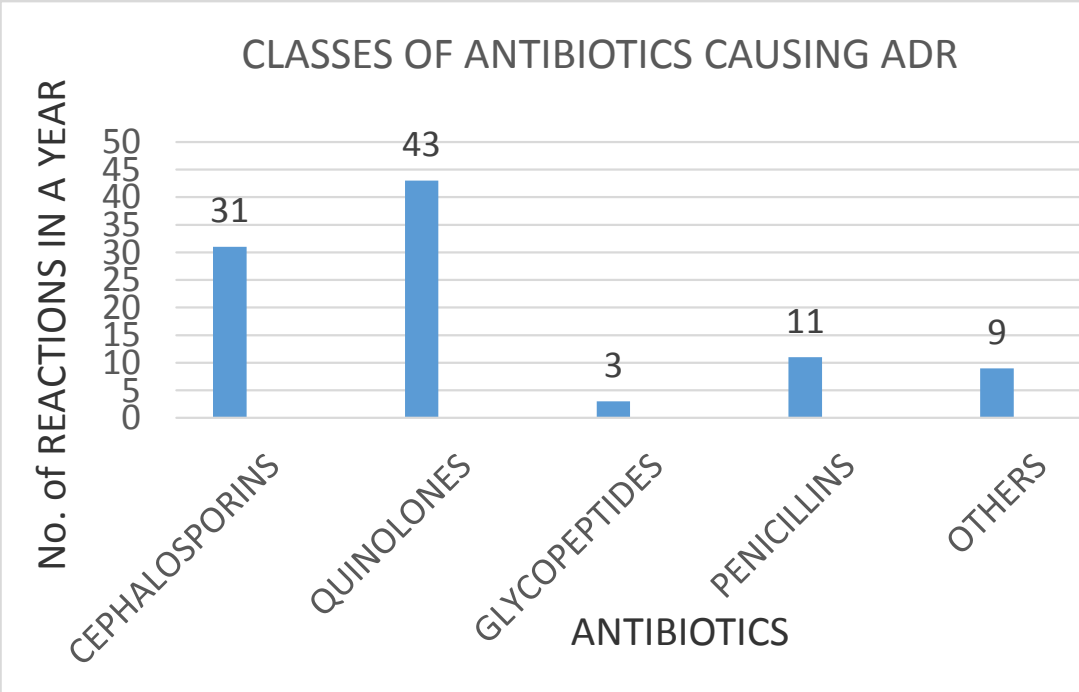
Methodology

This is a retrospective study which analyzes the ADRs of antibiotics in inpatients of Sri Ramachandra Medical College for a period of 1 year (May 2013 to May 2014). Reported ADRs was collected by the pharmacologists from the respective departments and maintained in a register in the pharmacovigilance centre. Causality assessment was done using WHO (UMC) Uppsala Monitoring Centre scale. In the WHO (UMC) scale an adverse drug reaction can be classified as certain, probable, possible, unlikely, unclassifiable and unclassified. ADR severity was classified into mild, moderate or severe based on the subjective assessment.

Patients of all age group are included in this study. [9] The data for the study were taken from this register which has the details filled in the adverse drug reaction form.

RESULTS

Analysis of ADRs during the study period revealed a total number of adverse drug reactions of 136 for a period of one year and adverse drug reaction due to antibiotics in our hospital was 97 with the female predominance of 60. Skin was the most commonly involved organ and respiratory system was involved to some extent. Reporting of ADR was maximum in the surgery department – 42, followed by medicine department- 26, pediatrics department- 14, OBG department- 10, others- 5. Results revealed that out of 97 ADRs reported, age group of 40 to 50 years were more accounted,(29 reactions) and 15 reactions were reported in the age group of 60 to 70 years. Quinolones was the most commonly involved antibiotic which had 43 reactions, followed by cephalosporins- 31 reactions, penicillins (amoxicillin)- 11 reactions, glycopeptide antibiotics(vancomycin) - 3 reactions and others- 9 reactions. Severity of the adverse drug reactions were classified by subjective assessment and most of the reactions were mild- 76. Moderate reactions was16 in number and severe reactions was 5. As per the WHO (UMC) scale, [6] majority of the reactions were probable, with a less number of certain and possible reactions.



DISCUSSION

In this there is a predominance of female patients accounting for antibiotic induced ADR. This might be due to a larger population of female patients admitted in the hospital. Surgery, medicine and pediatrics was the most commonly involved departments as the need for antibiotic use will be more in these departments. Fluoroquinolones, mainly ciprofloxacin and

cephalosporins, especially cefoperazone sulbactum were the most commonly used antibiotics in our hospital settings and so this accounted for a maximum number of ADRs. The prevalence rate of adverse reactions due to antibiotics in this study was comparatively low when compared to other studies. This was due to the effective intervention and co-operation of health care professionals in our hospital.

CONCLUSION

Antibiotics are a key component of infection management and prevention. Their use is risky and medication-related errors are among the most frequent medical errors and it is the most common threat to the health of the patient. [10] A good knowledge of the antibiotics and the mechanism of adverse drug reaction will help in preventing the reactions. [11] In developing countries like India, Pharmacovigilance Programme is facing a lot of difficulty because of drugs being sold by pharmacists without prescription, antibiotic misuse, and also the pharmacovigilance centres are running in shortage of well trained staffs and money. This can be improved by creating awareness among the health care professionals and placing an ADR drop boxes in each ward and appreciating the reporters through thank you letters. [8]

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